REMARKS

The Office Action mailed September 10, 2007 has been carefully considered by Applicant. Reconsideration is respectfully requested in view of the remarks that follow.

Claim Rejections Under 35 U.S.C. §112

Claim 1 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

I. In paragraph 2 of the Detailed Action, the Examiner states: "*Claim 1 line 9, fails to explain what role does 'at least two planar images' play in the overall process and need they be discreet or incorporated into a 3D volume?*"

The Examiner is referred to the application at page 12, line 17, through page 13, line 17. Specifically, in all embodiments of the invention, the body portion 9 is radiated with x-rays R coming successively from at least two different directions D1 and D2 and/or D3 to form at least two planar images of the body portion, i.e. two stereoscopic images, whereafter a three-dimensional image data is derived from at least two data sets that correspond to the planar images formed on the imaging detector and from said at least two directions. This 3D image data carries information about the internal structure of the body portion, and accordingly the inside locations of the lesions, i.e. inside location data or coordinates of the lesion inside the body portion, can be calculated from that image data in a predetermined three-dimensional coordinate system, which has two coordinate values in a plane substantially parallel to the platform 1 and a coordinate value in a direction perpendicular to the platform.

Here, the role of the "*at least two planar images and respective image data of said body portion*" are utilized (as described above) in the subsequent claim step "*calculating, from said at least two image data and from said at least two directions, said inside location in a predetermined three-dimensional coordinate system having two coordinate*

values in a plane substantially parallel to said platform". In view of the specification and the subsequent claim step, applicant believes the claims are quite clear and satisfy the requirements of Section 112.

II. In paragraph 3 of the Detailed Action, the Examiner states "*Claim 1 line 15, fails to explain the estimated configuration all of a line (boundary contour), area and 3D relief map of the uncompressed region or is it always only a two-dimensional feature that serves to define the entry point?*"

The Applicant does not understand the meaning of the above-quoted statement. The specification states at page 13, lines 9-17:

> In the arrangement of FIGS. 2A and 2B the configuration of the tissue surface 3 is estimated without any markers or invasive instruments, but its form and position is calculated solely from the image data received by the image detector and the radiation directions. This is possible because the atmosphere at any point above the body portion deviates from any point inside the body portion, causing traces in the two-dimensional image data and accordingly in the three-dimensional image data, too. On the basis of the inside location data an entering point E for the invasive instrument 10 within the accessible area, that is in the area of the opening 12, of the surface 3 is selected.

The specification therefore is believed to completely support the recitation of claim 1, and claim 1 is believed to adhere to the requirements of §112, second paragraph.

If the Examiner has further questions regarding the invention or requires additional clarification, he is encouraged to contact the undersigned attorney to discuss this matter by telephone.

Claim Rejections Under 35 U.S.C. §102 and §103

Claims 1 and 15 have been rejected under 35 U.S.C. §102(b) as being anticipated by Cosman 5,947,981. Claim 40 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Cosman '981. Claims 2-14, 16-28, 30-39 and 41-48 have been rejected

under 35 U.S.C. §103(a) as being unpatentable over Cosman '981 in view of Derechinsky et al U.S. Patent No. 4,583,537.

In general, the present application is directed to a method for locating a suspected lesion in an x-rayed body and then facilitating a reliable biopsy sample from a precise location at the lesion. In contrast, the art cited by the Examiner is simply directed to radiation of a tumor. That is, the references cited by the Examiner do not relate whatsoever to introduction of an invasive instrument for the purposes of taking biopsy samples. In addition, the art cited by the Examiner does not in any way, shape or form teach or suggest methods or systems that facilitate accuracy in taking of a biopsy sample reliably and precisely, per the method claimed in the present application. The clear differences between the cited references and the present application become even more evident in view of the following discussion of particular claim limitations.

In view of the clear differences between the claimed method and the references cited by the Examiner, as discussed below, withdrawal of the rejections is respectfully requested.

Claim 1

I. The cited art does not teach or suggest the claimed step of "*estimating a configuration of said tissue surface from said image data*".

By the present application, it is recognized as necessary to accurately estimate the configuration of the tissue surface to enable accurate placement of a mechanically invasive instrument that is forwarded from the tissue surface into the tumor/ lesion. And, as discussed below under subsection IV, estimation of the distance between the invasion point and the lesion is further necessary in order to provide a precise invasion operation. Cosman '981 and Derechinsky et al '537 do not relate whatsoever to introduction of any

invasive instrument. Rather, the intention of both Cosman and Derechinsky et al was to radiate a tumor.[1]

Even if for some reason one skilled in the art were to try and use some non-described mechanically invasive probe to invade the tumor based of the methods taught by Cosman '981 or Derechinsky et al '537, the probe would apparently have to be guided with the aid of the immobilizer construction of Cosman '981 (not with any distance from the tissue surface). Such guiding is not described in the art and would in fact be very complicated indeed based upon the systems of Cosman '981 and Derechinsky et al '537, and would be largely unpractical. For the purposes of Cosman '981 and Derechinsky et al '537, (i.e. radiating of a target/ tumor) there is no need to know anything about the tissue surface, its configuration or position. Rather, it is only necessary to know the position of the tumor/lesion with respect to some permanent and stationary structure of the radiation device. This is simply because the radiation beams do not have and cannot have any length, but only a direction.[2] The needlessness of a surface in their context is the reason why Cosman '981 and Derechinsky et al '537 fail to even mention the tissue surface and its configuration or position.

II. The cited art does not teach or suggest the claimed step of "*selecting an entering point for an invasive instrument within said surface area*".

Clearly, because neither Cosman '981 nor Derechinsky et al '537 teach or suggest the use of an invasive instrument, neither of these references teach the step of selecting an entry point. The intention of the cited references is to radiate the tumor either by x-ray beams or radiation beams from an accelerator[3] as described above. The prior art

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[1] See Cosman: column 1, lines 29-32 and lines 66-67, column 2, lines 3-5 and 20-23; Derechinsky: column 1, line 29-column 2, line 24.

[2] For an explanation: therapeutical or healing radiation is performed so as to direct several radiation beams from different directions, either simultaneously or consecutively, to the tumor/target, whereupon said tumor/target receives high dosages of radiation, while the surrounding healthy tissue gets only low dosages of radiation.

[3] "*... delivery of radiation from a LINAC through a collimator system such as 17 can be directed to the stereotactic target coordinates of the selected target position.*" and "*... probe or external irradiation to targets in the head and neck region.*" [Cosman: column1, lines 29-32 and lines 66-67], "*... for a patient who must be placed on a radiation*

arrangements utilize several radiating beams from different directions; however, the entry points of these beams are totally unessential, because the beams have directions only (but no length).

III. The cited art does not teach or suggest the claimed step of "*determining a moving direction for said invasive instrument*".

Neither Cosman '981 nor Derechinsky et al '537 determine any moving direction of an invasive instrument. Rather, both Cosman '981 and Derechinsky et al '537 used radiation beams only and determined the non-variable position for the stationary target (tumor)[4] using a localizer or immobilizer construction or frame assembly including rods or arms or the like. The purpose of these components is to keep the head of the patient immovable, and to be included in the image (screws or straps or dental trays or the like for immobilization of the patient are not invasive instruments). Neither Cosman '981 nor Derechinsky et al '537 mention any mechanical component to be moved from outside the patient's body into the patient's body, i.e. there is no transported or invading components disclosed, and consequently there is and cannot be any invasive moving direction in the devices or systems of Cosman '981 or Derechinsky et al '537, per claim 1.

IV. The cited art fail to teach or suggest the claimed step of "*calculating a distance between said entering point on said estimate surface area and said calculated inside location in said moving direction*".

Neither of the cited references define any entering point, nor any estimated surface area, and consequently they do not calculate and cannot calculate any distance between

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couch repeatedly for fractionated radiation treatments." and "*... to enable high dose delivery to cancerous tumors and minimal dose delivery to critical or radio-sensitive structures nearby.*" [Cosman: column 2, lines 3-5 and 20-23] etc. "*Radioactive interstitial implantation*", "*External radiation with lineal accelerator*", "*Radiation with Cobalt 60 with multiple fixed sources*" and "*Radiation with the convergent multibeam unit*" etc. [Derechinsky: column 1, line 29-column 2, line 24].

[4] Cosman '981: e.g. column 5, line 23.

the entering point and the calculated inside point of the lesion. Instead, Cosman '981 teaches that because of the slopes of rods...

> the index identification is accordingly very simple in terms of mapping of distances between index spots from the rods and diagonals and vertical lever or slice position of the two-dimensional image slice data. The index data from such a graphic reference means enables a referencing of the scanned image data and patient's anatomy relative to the mechanical structures of the over-arm and/or to the couch. In this way, the anatomical data of the patient can be referenced to external apparatus. See Cosman '981, column 5, lines 29-45.

Therefore, according to Cosman '981, a system is provided that gives some vague index identification, mapping or referencing. Cosman '981 does not define or explain specifically what is meant by this technology. Derechinsky et al '537 also does not calculate anything even close to this type of information.

V. The cited art also fails to teach or suggest the claimed step of "*displaying or outputting said moving direction in said distance, and tracing or displaying or outputting said two coordinate values, for guiding said invasive instrument*".

Neither Cosman '981 nor Derechinsky et al '537 provide invasive moving direction and invasive distance, and consequently they cannot display these values for any purpose. Cosman '981 mentions a "stereotactic probe"[5] which instrument is not described, but which is typically used for treatment of deep-seeded brain tumors, whereupon the probe is expressly always attached to a stationary frame assembly, with the aid of which the patient's head is immobilized. Cosman '981 does not describe any moving or any values that could or should be used in the context of the mentioned "probe". Derechinsky et al '537 discloses a multi-beam unit for radiation, especially a linear accelerator, for radiation treatment only.[6] Accordingly, Derechinsky et al '537 describes a radiation device that could be used for healing therapy by radiation in a way described above. However, the

[5] See Cosman '981, column 8, line 7
[6] See Derechinsky et al '537 title, column 1, lines 6-7 and 55-56, column 5, lines 56-58.

system of Derechinsky et al '537 has nothing to do with moving direction and distance of an invasive instrument.

Claims 2-14

Claims 2-14 depend directly or indirectly from claim 1 and are thus believed allowable for the reasons stated above, as well as the subject matter recited therein.

Claim 15

Claim 15 includes several limitations that are comparable to the limitations discussed above regarding claim 1. For example, claim 15 requires the step of "*deriving inside location data and outside location data from at least two image data and from at least two directions*". The claimed "outside location" can be analogous to the "tissue surface" of claim 1, and consequently the same conclusions apply as discussed above regarding claim 1.

Claim 15 further includes the steps of

- *calculating said inside location in a predetermined three-dimensional coordinate system from said inside location data with two coordinate values in a plane substantially parallel to said platform*;
- *estimating a configuration of said tissue surface from said outside location data*;
- *selecting an entering point for an invasive instrument within said surface area*;
- *determining a moving direction for said invasive instrument*;
- *calculating a distance between said estimated tissue surface and said calculated inside location in said moving direction; and*
- *displaying or outputting said moving direction and said distance, and tracing or displaying or outputting said two coordinate values, for guiding said invasive instrument.*

These limitations are also not taught or suggested by the cited the art, per the comments provided above regarding claim 1.

Claims 16-28

Claims 16-28 depend directly or indirectly from claim 15 and are thus believed allowable for the reasons stated above, as well as the detailed subject matter recited therein.

Claim 29

Claim 29 includes the method steps of:

- *deriving inside location data and outside location data from said at least two image data and from said at least two directions;*
- *calculating a direction and a respective distance between said marker and said calculated inside location for entering an invasive instrument; and*
- *displaying or outputting said direction and said distance for guiding said invasive instrument*

None of the above-referenced limitations are found in the references for the very reasons discussed above regarding claim 1. As such, withdrawal of the rejection of claim 29 is requested.

Claims 30-39

Claims 30-39 depend directly or indirectly from claim 29 and are thus believed allowable for the reasons stated above, as well as the detailed subject matter recited therein.

Claim 40

Claim 40 recites the step of "*determining a moving direction for an invasive instrument having a tip*".

The conclusions discussed above regarding claim 1 apply here as well. This step is neither taught nor suggested by the cited art.

Claim 40 further includes the step of "*radiating said body portion, after inserting an invasive instrument into said body portion or in contact or approaching a contact with said tissue surface, with x-rays coming from at least a second direction to form at least a second individual image of said body portion*".

Neither Cosman '981 nor Derechinsky et al '537 teach or suggest radiating a patient's body after insertion of a non-existing invasive instrument. Clearly, the references further do not provide these measures to have additional images for measuring purposes. There is nothing whatsoever like this step, nor any respective teaching disclosed in the referenced prior art. Cosman '981 and Derechinsky et al '537 are incommensurable with the invention claimed in the present application.

Claim 40 further includes the step of "*measuring a spacing between said tip and said suspected lesion from said second image*"

As discussed above, the cited references do not relate to the use of an invasive instrument and there is no teaching of image forming radiation after insertion of an invasive instrument in the art. Consequently, there is no spacing that is or even could be measured by the referenced art. Further, Cosman and Derechinsky et al measured and can only be understood to measure things that are part of the immobilizer construction or frame construction, respectively. The cited art does not allow measuring of a movable instrument. The cited art completely lacks this process step.

Claim 40 further includes the steps of:

- *calculating, from said spacing and from said second direction, a distance between said tip and said suspected lesion in said moving direction; and*
- *displaying or outputting said distance and said moving direction for guiding said invasive instrument.*

For the same reasons discussed above, the art fails to teach or suggest these steps.

Claims 41-48

Claims 41-48 depend directly or indirectly from claim 40 and are thus believed allowable for the reasons stated above, as well as the detailed subject matter recited therein.

Conclusion

The present application is believed in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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